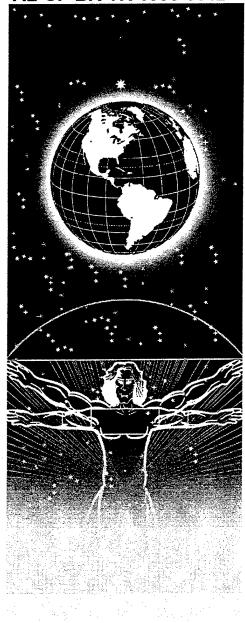
AL-CF-BR-TR-1998-0012



UNITED STATES AIR FORCE ARMSTRONG LABORATORY

TESTING AND EVALUATION OF THE MEDICAL RESEARCH LABORATORIES, INC., 360SLX CARDIAC MONITOR/PACEMAKER/DEFIBRILLATOR SYSTEM

Edward Hade

KRUG LIFE SCIENCES
2504 Gillingham Drive, STE 25
Brooks Air Force Base TX 78235-5104

Jacqueline D. Hale

CREW SYSTEMS DIRECTORATE
CREW TECHNOLOGY DIVISION
2504 Gillingham Drive, STE 25
Brooks Air Force Base TX 78235-5104

May 1998

19980721 062

NOTICES

This final technical report was submitted by personnel of the Systems Research Branch, Crew Technology Division, Armstrong Laboratory, AFMC, Brooks Air Force Base, Texas, under job order 7184-56-01.

This report was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency thereof, nor any of their employees, nor any of their contractors, subcontractors, or their employees, makes any warranty, expressed or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise, does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government or any agency, contractor, or subcontractor thereof. The views and opinions of the authors expressed herein do not necessarily state or reflect those of the United States Government or any agency, contractor, or subcontractor thereof.

When Government drawings, specifications, or other data are used for any purpose other than in connection with a definitely Government-related procurement, the United States Government incurs no responsibility or any obligation whatsoever. The fact that the Government may have formulated or in any way supplied the said drawings, specifications, or other data, is not to be regarded by implication, or otherwise in any manner construed, as licensing the holder or any other person or corporation; or as conveying any rights or permission to manufacture, use or sell any patented invention that may in any way be related thereto.

The Office of Public Affairs has reviewed this report, and it is releasable to the National Technical Information Service, where it will be available to the general public, including foreign nationals.

This report has been reviewed and is approved for publication.

Government agencies and their contractors registered with Defense Technical Information Center (DTIC) should direct requests for copies to: Defense Technical Information Center, 8725 John J. Kingman Rd., STE 0944, Ft. Belvoir, VA 22060-6218.

Non-Government agencies may purchase copies of this report from: National Technical Information Services (NTIS), 5285 Port Royal Road, Springfield, VA 22161-2103.

JACQUELINE D. HALE, Lt Col, USAF, NC

Chief, Aeromedical Research

scarelie Offile

F. Wesley Bay

F. WESLEY BAUMGARDNER, PhD.

Acting Chief, Crew Technology Division

REPORT DOCUMENTATION PAGE

Form Approved OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Datis History VA 2202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

Davis Highway, Suite 1204, Arlington, VA 22202-43	02, and to the Office of M			ND DATES COVERED
1. AGENOT GOE GRET TESSYS BIGINA	MAY			inal, September 1996
4. TITLE AND SUBTITLE	MAI	76		5. FUNDING NUMBERS
Testing and Evaluation of the Medic	al Research Labo	ratories, Ir	nc., 360SLx Cardiac	PE: 62202F
Monitor/Pacemaker/Defibrillator System			,	PR: 7184
6. AUTHOR(S)				TA: 56
				WU: 01
Edward Hade				
Jacqueline D. Hale				
7. PERFORMING ORGANIZATION NAM	IE(S) AND ADDRES	SS(ES)		8. PERFORMING ORGANIZATION REPORT NUMBER
Systems Research Branch				
2504 Gillingham Dr. STE 25				
Brooks AFB TX 78235-5104 9. SPONSORING/MONITORING AGENC	Y NAME(S) AND A	ADDRESS(E	S)	10. SPONSORING/MONITORING
Air Force Research Laboratory (AFM				AGENCY REPORT NUMBER
Human Effectiveness Directorate	•			AT CE DD TD 1009 0012
Flight Stress Protection Division				AL-CF-BR-TR-1998-0012
2504 Gillingham Dr. STE 25				
Brooks AFB TX 78235-5104				
11. SUPPLEMENTARY NOTES				
12a, DISTRIBUTION AVAILABILITY STA	TEMENT			12b. DISTRIBUTION CODE
				•
Approved for public release; distribu	tion unlimited.			
•				İ
13. ABSTRACT (Maximum 200 words)				
	(ACDI) I	1-1 260	CI i	lies monitor defibrillator and
The Medical Research Laboratori pacemaker that offers synchronized d				
MRL Rapid Charger/Conditioner is				
12 VDC converter plugs directly into	the 260 SI wand	i allowe th	cx to be powered from	rom the aircraft's 28 VDC electrical
bus. Additionally, the unit can recei) the 300 SLX and	anows ur	12 volt 1 2 or 1 7 or	on hour Ni-Cad battery nack. The 360
SLx weighs 17.8 lbs and is 6.25 in.			: 12 voit, 1.5 of 1.7 at	np nour 141-cad battery pack. The sec
SLX weighs 17.8 lbs and is 0.25 m.	д 10.75 ш. д 15.	.22 ш.		
14. SUBJECT TERMS				15. NUMBER OF PAGES
	l equipment	Pacemake	r	
360 approved aerome		Defibrilla	ator	16. PRICE CODE
	c monitor		Research Laboratories	
17. SECURITY CLASSIFICATION 18. S	SECURITY CLASSIF	ICATION	19. SECURITY CLASSIF	ICATION 20. LIMITATION OF ABSTRAC
OF REPORT	OF THIS PAGE	i	OF ABSTRACT	
UNCLASSIFIED	UNCLASSIFII	ED	UNCLASSIFII	ED UL

TABLE OF CONTENTS

BACKGROUND	1
DESCRIPTION	1
PROCEDURES	3
INITIAL INSPECTION AND TEST PREPARATION	3
TEST SETUP	4
PERFORMANCE CHECK	5
VIBRATION	5
ELECTROMAGNETIC COMPATIBILITY	6
THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS	8
HYPOBARIC CONDITIONS	9
AIRBORNE PERFORMANCE	9
EVALUATION RESULTS	10
INITIAL INSPECTION	10
VIBRATION	10
ELECTROMAGNETIC COMPATIBILITY	10
THERMAL/HUMIDITY ENVIRONMENTAL CONDITONS	11
HYPOBARIC CONDITIONS	11
AIRBORNE PERFORMANCE	11
SUMMARY	11
REFERENCES	13
APPENDIX	14
LIST OF FIGURES	
Figure 1. MRL 360SL ^X System	2
Figure 2. Test Setup	4
Figure 3. Vibration Table Mounting	5
Figure 4. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17	6

ACKNOWLEDGMENTS

We would like to thank those who helped and provided advice during the evaluation of the $360 SL^{X}$ System. We would particularly like to thank:

Mr Douglas Townsend TSgt Butch Blake TSgt Allen Jones

TESTING AND EVALUATION OF THE MEDICAL RESEARCH LABORATORIES, INC., 360SL^X CARDIAC MONITOR/PACEMAKER/DEFIBRILLATOR SYSTEM

BACKGROUND

Representatives of Medical Research Laboratories, Inc. requested Aeromedical Research evaluate and certify their $360 \mathrm{SL}^X$ System for use on-board USAF aeromedical evacuation aircraft. Components of the $360 \mathrm{SL}^X$ System included the $360 \mathrm{SL}^X$ Cardiac Monitor/Pacemaker/Defibrillator, MRL Rapid Charger Conditioner, and the MRL 28 to 12 VDC Converter. All components of the $360 \mathrm{SL}^X$ System were tested for airworthiness. Throughout this report the term $360 \mathrm{SL}^X$ refers to the $360 \mathrm{SL}^X$ Cardiac Monitor/Pacemaker/Defibrillator, while the term $360 \mathrm{SL}^X$ System refers to the $360 \mathrm{SL}^X$ Cardiac Monitor/Pacemaker/Defibrillator, MRL Rapid Charger Conditioner, and the MRL 28 to 12 volt DC Converter.

DESCRIPTION

The $360 \mathrm{SL^X}$ is a portable cardiac monitor, defibrillator and pacemaker that offers synchronized defibrillation, electrocardiogram monitoring, and noninvasive temporary pacing (Fig. 1). The MRL Rapid Charger/Conditioner is designed to allow the $360 \mathrm{SL^X}$ to be powered from a 120 VAC/60 Hz source. The 28 to 12 volt DC Converter plugs directly into the $360 \mathrm{SL^X}$ and allows the unit to be powered from the aircraft's 28 volt DC electrical bus. Additionally, the $360 \mathrm{SL^X}$ can receive power via a rechargeable 12 volt, 1.3 or 1.7 Amp hour Ni-Cad battery pack. The duration of an individual battery's life varies as a function of the $360 \mathrm{SL^X}$'s operating mode as well as the level and frequency of defibrillations. The specification for the battery life defines a range of 1.9 to 2.25 hours.

The defibrillator is capable of delivering up to 360 joules of energy. It may be used in synchronized mode for performance of synchronized cardioversion by using the R-wave of the patient's ECG as a timing reference. The MRL $360 \mathrm{SL}^{\mathrm{X}}$ uses conventional paddles or disposable, pre-gelled, MRL Pacing Electrodes.

The $360 SL^X$ contains a non-fade monitor for observation of the patient's cardiac rhythm. The monitor displays the ECG in moving trace mode at 25 mm/sec.

A strip chart recorder is provided to document events. The strip recorder operates in either the (A) Auto (the chart recorder is in standby condition and will run for 15 seconds, including eight seconds of stored ECG when the defibrillator is fired) or the (B) On (the chart recorder will run continuously, printing ECG waveform and annotating status) mode.

The 360SL^X will defibrillate, cardiovert and monitor using the MRL 360SL^X defibrillation paddles. MRL has labeled one of these Apex and one Sternum. The Apex defibrillator paddle is positioned near cardiac apex for "paddle pickup" of ECG signal to be displayed on the monitor while the sternum defibrillator paddle is positioned on the sternum. There is a remote charge button located on the Apex paddle. Each paddle has a discharge control (red fire button) which must operate in conjunction with each other in order to discharge; depressing only one control will not cause the paddles to discharge. If the paddles are charged and not actively discharged within 60 seconds, the energy will automatically discharge internally.

The 360SL^X incorporates a noninvasive temporary pacing option with a control panel located adjacent to the monitor. The pacer is a demand pacemaker consisting of a pulse generator and ECG sensing circuitry. The output current of the pacemaker is continuously variable up to 180 mA and the rate is continuously variable from 30-180 pulses per minute (ppm).

The following information defines the general specifications of the 360SL^X defibrillator. Size: 35.6 X 27.3 X 16 cm (6.25 X 10.75 X 15.25 in). Weight: 7.3 Kg (17.8 lbs). Heart Rate Range: 30-300 BPM. Pacing Rate Range: 30-180 BPM. Pacing Current Range: 30-180 mA in 12 discrete ranges. Available Energy Range: 0-360 joules in eight energy levels. Lead Selection: paddles, I, II, III. Printer speed: 25 mm/sec.

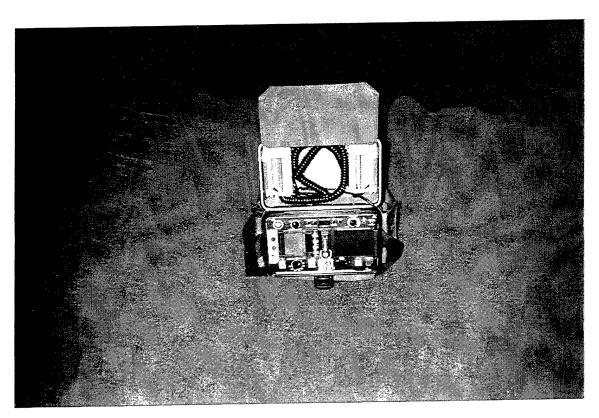


Figure 1. MRL 360SLX System

PROCEDURES

Test methods and performance criteria were derived from various military standards (Reference List 1-4), nationally recognized performance guidelines (5), and manufacturer's literature (6). The Aeromedical Research Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (6). A test setup and performance check were developed specific to this product to verify proper functioning of the equipment during various testing conditions.

The device was subjected to various laboratory and inflight tests to observe and evaluate its performance under anticipated operational conditions.

- 1. Initial Inspection
- 2. Vibration
- 3. Electromagnetic Interference (EMI)
- 4. Thermal/ Humidity Environmental Conditions, encompassing:
 - a. Hot Operation
 - b. Cold Operation
 - c. Humidity
 - d. Hot Temperature Storage
 - e. Cold Temperature Storage
- 5. Hypobaric Condition
 - a. Cabin Pressure/Altitude
 - b. Rapid Decompression to Ambient Pressure
- 6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

a. The 360SL^X System was inspected for quality of workmanship, production techniques and possible damage incurred during shipment.

- b. The 360SL^X System was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (8), Electrical Shock Hazards, AFI 41-203 (9), and Equipment Management in Hospitals, AFI 41-201 (10). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz.
- c. The $360 SL^{X}$ System was examined to ensure it met basic requirements for good human factors design as outlined in MIL-STD 1472 (4).
- d. A test setup and performance check were developed to evaluate the $360 \mathrm{SL}^{\mathrm{X}}$ System's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

One, of the following two analyzers, was connected to the ECG port on the monitor and provided the ECG waveform for the $360 \mathrm{SL}^{\mathrm{X}}$ during the monitor portion of testing: the Lionheart Multiparameter Simulator or the Impulse 4000 Analyzer. The three ECG leads were attached to the corresponding color-coded receptacles on the analyzer. The Lionheart settings were the following: Lead Select, I/II; ECG amplitude, 1.0; and ECG BPM, beats per minute, 60. The Impulse selections were the following: ECG mode, Normal Sinus Group (NORM), and 60 beats per minute. The Impulse 4000 also analyzed the defibrillator portion of the $360 \mathrm{SL}^{\mathrm{X}}$ when it operated in the DEFIB mode. One Ni-Cad battery pack, 28 to $12 \mathrm{VDC}$ Converter or the MRL Rapid Charger Conditioner provided power to the $360 \mathrm{SL}^{\mathrm{X}}$. The $360 \mathrm{SL}^{\mathrm{X}}$ was configured as follows: Lead Select, II; ECG size that allowed for the largest view of the waveform; pacer settings on $100 \mathrm{~mA}$ and $100 \mathrm{~BPM}$ when pacer was activated; SYNC mode selected (where applicable); when in SYNC mode, ECG size control was adjusted such that the SYNC marker was positioned on the upper portion of the QRS complex.

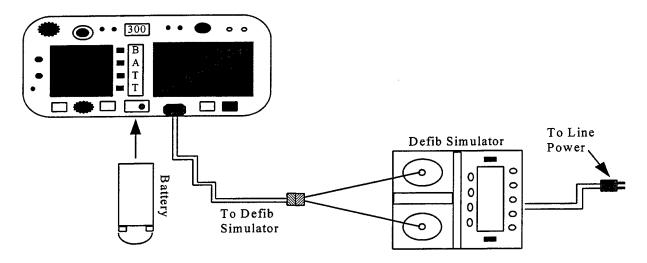


Figure 2. Test Setup

PERFORMANCE CHECK

As the 360SL^X monitored the ECG waveform, defibrillator energy levels were selected and the paddles subsequently discharged into the energy determining device. The performance check included discharging the paddles a number of times at both a high-energy level, 360 joules, and a low-energy level, 10 joules. Additionally, the baseline performance check included testing synchronized defibrillation at an energy level of 50 joules. The ECG trace was used to visually confirm whether or not the defibrillator fired at the appropriate location on the waveform. The performance check concluded with the verification of the pacer output and recorder function. The Impulse 4000 monitored the pacer, ensuring the accuracy of the pacing frequency and amplitude.

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (3). This testing involved a set of operational tests performed along each of the 360SLX System's three axes - X, Y, and Z, with the 360SLX System's components mounted on the NATO litter segment on the vibration table as they would be in the aircraft (Figure 3). They were subjected to vibration curves with similar levels and lengths as those derived from MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17 (Figure 4).

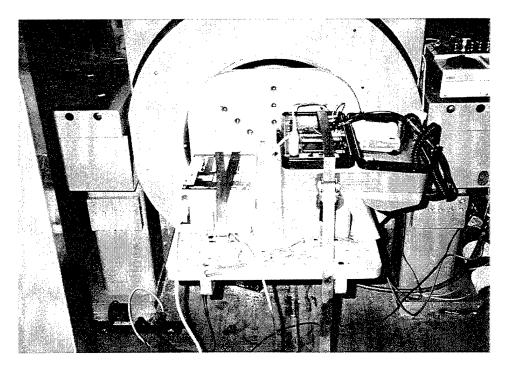
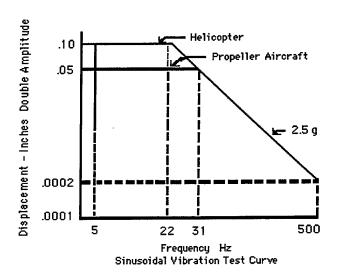


Figure 3. Vibration Table Mounting



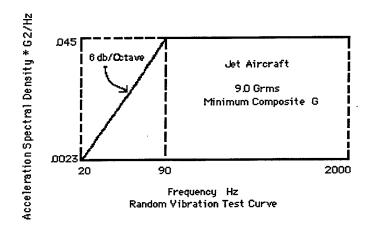


Figure 4. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Ensuring the safety of everyone on board is the driving factor to accessing the effects of excessive electromagnetic emissions and their influence on aircraft navigation and communication equipment. Additionally, medical devices may be susceptible to fields generated by the aircraft equipment or other medical devices, and malfunction in their presence.

The 360SLX System was evaluated for compliance with MIL-STD-461D (1) and 462D (2). Southwest Research Institute performed all of the EMI evaluation with the exception of CS 115, which was performed by ASC/ENAI, Wright-Patterson AFB in their electromagnetic compatibility facility. ASC/ENAI evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

- a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to 18 GHz.": For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz 1 GHz. This test determined the amount of EMI emitted by the equipment during its operation. This test was performed to ensure that the device does not affect other pieces of equipment that may be susceptible to electromagnetic emissions (i.e., aircraft navigation and communication equipment).
- b. Conducted Emissions (CE-102), "Conducted Emissions, Power Leads, 10 kHz to 10 MHz.": For Air Force aircraft applications, conducted emissions were tested throughout the entire band of 10 kHz 10 MHz. This test measured emissions generated by the medical device along its power supply lines. This test was performed to ensure that operating the device using line power does not affect other items connected to the same power source, particularly aircraft systems.
- c. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (field strength values from Table IV, category Aircraft Internal, of 461D). This test determined whether or not the device would withstand pre-defined levels of EMI generated by antennas both internal and external to the aircraft.
- d. Conducted Susceptibility (CS-101), "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz.": For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test determined whether the components would "withstand ripple voltages associated with allowable distortion of power source voltage wave forms."
- e. Conducted Susceptibility (CS-114), "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz.": For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout a narrower portion of the frequency band, from 10 kHz to 200 MHz. This test was performed to determine whether "simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test."
- f. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test was performed to ensure the 360SLX System could withstand the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse."

During emissions testing, all options were operating for the duration of the test to create the "worst case" emissions scenario. Throughout the testing, the Recorder (printer) ran continuously and the QRS beep sounded at maximum volume. For susceptibility testing, the $360 \mathrm{SL}^{\mathrm{X}}$ System was operated in the monitoring mode. The paddles were charged and discharged at intervals for two reasons. First, it allowed researchers to crudely determine if EMI would

cause the equipment to defibrillate at times other than when the operator depressed the discharge buttons; and second, energy defibrillation levels and monitor function could be confirmed. Aeromedical Research personnel were unable to test the SYNC function because it would have required them to be subjected to dangerous levels of electromagnetic radiation. For both emissions and susceptibility testing, the 360SLX System was tested for operation on 115 VAC/60 Hz, 28 VDC and internal batteries.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing is critical to determine if aeromedical equipment can be stored and operated during severe environmental conditions "without experiencing physical damage or deterioration in performance." (3) Extreme environmental conditions can have numerous incapacitating effects on medical equipment including, but not limited to, the following: changes in material characteristics and material dimensions, possible overheating, changes in lubricant viscosity, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Armstrong Laboratory research chambers operated and monitored by chamber operations personnel assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory, Brooks AFB, TX. The 360SLX System was placed in the center of the environmental chamber. All input and output cables and wires were routed through a port in the chamber wall, which was subsequently sealed with a precut sponge plug. The other components of the test setup remained outside the chamber. For operational tests, the 360SLX System was monitored throughout testing, and a performance check was conducted every fifteen minutes. For storage tests, the 360SLX System was placed in the chamber and remained nonoperational throughout the storage portion of the test. Upon completion of this test the chamber was brought to standard ambient conditions. AR personnel then conducted a performance test and monitored the unit for one hour to verify successful operation. The following describe the conditions of the environmental tests performed:

- a. Humidity: $94 \pm 4\%$ RH, $85^{\circ}F \pm 3.6^{\circ}F$ ($29.5^{\circ}C \pm 2^{\circ}C$) for 4 hrs
- b. Hot Temp Operation: $120^{\circ}F \pm 3.6^{\circ}F$ ($49^{\circ}C \pm 2^{\circ}C$) for 2 hrs
- c. Cold Temp Operation: $32^{\circ}F \pm 7.2^{\circ}F$ ($0^{\circ}C \pm 4^{\circ}C$) for 2 hrs
- d. Hot Temp Storage: $140^{\circ}F \pm 3.6^{\circ}F$ ($60^{\circ}C \pm 2^{\circ}C$) for 6 hrs
- e. Cold Temp Storage: $-40^{\circ}F \pm 3.6^{\circ}F (-40^{\circ}C \pm 2^{\circ}C)$ for 6 hrs

HYPOBARIC CONDITIONS

Testing was conducted in the Armstrong Laboratory research chambers operated and monitored by chamber operation personnel assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory, Brooks AFB, TX.

Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to the potential effects of barometric pressure changes on the equipment. A majority of the aircraft, which are characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabin atmosphere to barometric pressures equivalent to 8,000-10,000 feet above sea level. The differences in pressures can be critical to the effective operation of some medical equipment. Altitude testing consisted of operating the 360SLX System while ascending from ground level to 10,000 ft (maintaining altitude for one hour) and then descending back to ground, at rates of 5000 ft/min, while stopping at 2000 ft increments to allow for performance checks.

Rapid Decompression Testing: Rapid decompressions are caused by the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to determine how medical equipment will function during and after such a decompression to ensure that it will not endanger a patient, the aircraft personnel, or the aircraft itself. The 360SLX System operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft (2,438 meters) altitude. Then, the chamber altitude was brought to 40,000 ft (12,192 meters) over a period of 60 seconds, held at 40,000 ft while the equipment response was observed, and then returned to ground at a rate of 10,000-12,000 ft/min. The test was repeated twice with the decompressions occurring over seven and one seconds, respectively. The 360SLX System was monitored throughout the series of decompressions, including performance checks each time the unit returned to ground. The simulator equipment remained outside the chamber. Connectors joining the Impulse analyzer and the 360SLX and the power connector to the Power Charger were run through putty-sealed access ports in the chamber walls.

AIRBORNE PERFORMANCE

Airborne feasibility evaluations are a cost-effective and invaluable means of validating a piece of equipment's clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their actual environment, Aeromedical Research ensures that all pertinent patient care issues are adequately addressed by the test protocols. Ensuring safe and reliable operation of this medical equipment support device is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by an aircraft-qualified aeromedical flight nurse and aeromedical research technicians on board both a C-9 and C-130 aeromedical evacuation

mission. The 360SLX System was secured to the litter and evaluated throughout the flights by Aeromedical Research technicians as well as the other members of the aeromedical evacuation crew. Human factors characteristics, securing methods, and equipment setup times and locations were also evaluated.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification. Electrical safety test results showed all parameters to be within referenced guideline limits.

VIBRATION

The 360SLX Defibrillator and MRL Rapid Charger Conditioner operated within manufacturer's specifications throughout the vibration testing. The MRL 28-12 volt converter experienced one failure during vibration testing. A ceramic resistor broke away from its mounting bracket. The bracket/resistor assembly was modified by MRL and the unit operated within manufacturer's specifications upon retest.

ELECTROMAGNETIC COMPATIBILITY

WL/AAWA-2 tested the MRL 360SL^X System for susceptibility to the limits of MIL-STD-461D (CS115) and in accordance with MIL-STD-462D test methods. The system passed CS115 susceptibility test requirements when operated in the monitor mode. WL/AAWA-2 did not test the system in the pacer mode per manufacturer's request. The emissions testing (RE102 and CE102) and susceptibility testing (RS103, CS101, and CS114) were performed at Southwest Research Institute. All Southwest Research Institute testing was successfully completed, except when the system was operated in the pacer mode.

The MRL $360 \mathrm{SL}^{\mathrm{X}}$ System is certified per AFI 11-206 for operation during all phases of flight on all Air Force aircraft, except when the system is in the pacer mode.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The 360SLX System operated satisfactorily during all five phases of testing. Testing was conducted in the Armstrong Laboratory research chambers operated and monitored by chamber operations personnel assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory, Brooks AFB, TX.

HYPOBARIC CONDITIONS

- 1. Cabin Pressure/Altitude: The $360SL^X$ System performed in accordance with manufacturer's specifications throughout testing.
- 2. Rapid Decompression: The $360 \mathrm{SL}^{X}$ System operated satisfactorily following each decompression.

AIRBORNE PERFORMANCE

The inflight evaluation of the 360SL^X System was performed on a C-9 aeromedical evacuation mission and C-130 aeromedical readiness mission. Evaluation confirmed that the unit would operate successfully during all phases of flight. The Vanner Inverter successfully supplied power to the MRL Rapid Charger Conditioner during the C-130 mission. Analysis of flight data indicated this unit was easy to enplane and deplane and was compatible with aircraft electrical systems. Two significant human factors recommendations were noted during the airborne feasibility portion of airworthiness testing. The first recommendation was to change the relative position of the monitor assembly to the paddle(s) storage area by 180 degrees. This adjustment would place the paddles in a more "user friendly" position above the controls and CRT instead of below them. Another significant recommendation was to have the 360SL^X's carrying case modified. Nylon reinforced slots sewn in the back of the unit would keep the paddle storage compartment open and the paddles more accessible if needed in an emergency. The front slots would allow technicians to more appropriately secure the 360SL^X to the patient litter.

SUMMARY

Aeromedical Research found the MRL 360SL^X System to be acceptable for use on all U.S. Air Force aeromedical evacuation aircraft while operating on 115 VAC/60 Hz, 28 VDC or battery power with the recommendations and restrictions listed below. The 360SL^X System operated within expected parameters when subjected to environmental extremes and simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. The pacer portion of the 360SL^X Pacemaker/Defibrillator is not approved for use in the aeromedical evacuation aircraft; however, the inactive pacer portion will survive the

flight environment and be an available option for "off the aircraft" use. The following recommendations and operational restrictions accompany the airworthiness approval of the $360 \mathrm{SL}^{\mathrm{X}}$ System:

a. Add the following warning to the Operating Instructions and Service Manual:

WARNING: Restrictions for use on USAF aircraft: The pacing option is not to be operational at any time during flight. The MRL Rapid Charger Conditioner can only be used on 115 VAC/60 Hz.

- b. Attach a warning label near the pacer control panel that reads, "Do not operate pacer in flight."
- c. Attach a warning label on the MRL Rapid Charger Conditioner that reads, "Do not operate on 115 VAC/400 Hz."
- d. Inform Aircraft Commander that a cardiac monitor will be in use on board, and that they will be notified if defibrillation is to occur because of the possibility of electromagnetic interference with aircraft navigation and communication equipment.

REFERENCES

- 1. MIL-STD 461D, <u>Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.</u>
- 2. MIL-STD 462D, Measurement of EMI Characteristics.
- 2. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.
- 3. MIL-STD 1472, <u>Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.</u>
- 4. Emergency Care Research Institute (ECRI)
- 5. Medical Research Laboratories, Inc., 360SLX System, Operator's Manuals.
- 6. <u>Aeromedical Research Procedures Guide</u>, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.
- 7. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code
- 8. AFI 41-203, Electrical Shock Hazards
- 9. AFI 41-201, Equipment Management in Hospitals

APPENDIX MANUFACTURER'S SPECIFICATIONS OF THE MEDICAL RESEARCH LABORATORIES, INC. 360SLX SYSTEM

SPECIFICATIONS

General

Size

15.9 cm high x 27.3 cm wide x 38.7 cm long

(6.25 in x 10.75 in x 15.25 in).

Weight

7.3 kg. (16.1 lbs.)

Power

Ni-Cd; 1.3 Ah

Ni-Cd: 1.7 Ah

Patient Safety

All patient connections are electrically isolated.

Environmental Temperature: 0°C to 45°C (operating). -30°C to

65°C (storage and shipping). Humidity: 0% to

95% relative humidity, non-condensing.

Atmospheric

500 mm Hg to 780 mm Hg

Pressure

Pacemaker

Type

Asynchronous or Demand

Pulse

Rectangular, constant current.

Type

Pulse

Fixed 20 msec +/- 1 ms or 40 msec +/- 1 ms.

Duration

Pulse

Variable to 180 mA.

Amplitude

Pacing Rate

Variable from 30 to 180 bpm.

Output

Fully defibrillator protected (up to 360 watt/sec) and

Protection

isolated.

Defibrillator

Waveform

Truncated Exponential.

Output

Selectable at 5, 10, 20, 50, 100,

(delivered)

200, 300, 360 joules.

Energy

Control on unit front panel.

Selection

Charge Time

Less than 12 seconds. Depleted batteries will result

in a longer defibrillator charge time.

Synchronized

Synchronized defibrillator pulse to patient's R-

Mode wave.

Charge

Controls

Control on apex paddle and on front panel.

Electrode Area

12.8 sq. in (82.6 sq.cm)

Monitor and Displays

Patient

Via 3 lead ECG cable, paddles or electrodes.

Connection

Selectable by front panel switch.

Input Protection

Fully defibrillator protected.

Electrical Isolation

Input protected against high-voltage defibrillator

and Shielding pulses and radio frequency

interference.

Display Format

Non-fade, moving trace.

Screen Size

4.5 inches diagonally (114 mm), viewing area.

Recorder

Paper

Standard 40 mm thermal (grid width). 50 mm

(paper width).

Speed

25 mm/sec.

Delay

5.2 seconds.

Battery Packs

Type Ni-Cd

Voltage 1.3 Ah, 12 V 1.7 Ah, 12 V.

Recharge Time 5 hours for full recharge in MRL Rapid Charger

Recharge Time 5 hours for for Conditioner.

Operating Time Minimum 2.5 hours of monitoring or thirty (30) 360

joule discharges at 25°C or 1 hour 50 min. of pacing

and monitoring.

Charger Use MRL Rapid Charger Conditioner for

recharging battery packs.